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I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on May 9, 2002.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Dennis CARSON et al.

Serial No.: 09/265,191

Filing Date: March 10, 1999

For: IMMUNE STIMULATORY
COMPOSITIONS AND METHODS FOR
USE OF SAME TO ENHANCE THE
IMMUNE RESPONSE OF A HOST TO
AN ANTIGEN (AS AMENDED)

Examiner: Q. Nguyen

Group Art Unit: 1632

DECLARATION OF DENNIS A. CARSON, M.D.
PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Dennis A. Carson, M.D., declare as follows:

1. I am an inventor named in the above-referenced patent application, and am familiar with the contents thereof.
2. I currently reside at 14824 Vista del Oceano in Del Mar, California.
3. I am the Director of the Sam and Rose Stein Institute for Research on Aging at the University of California San Diego in La Jolla, California. I am also a Professor in the Department of Medicine at the University of California San Diego and an Adjunct Member of

the Department of Molecular and Experimental Medicine at The Scripps Research Institute in La Jolla, California. A copy of my Curriculum Vitae is attached.

4. I have worked in the area of administration of antigen in the form of an antigen encoding polynucleotide for more than 12 years. During the course of this work, I also worked with systems employing administration of antigen and am familiar with the scientific literature in the field of immune response due to antigen administration, whether the antigen administration is by antigen per se or by a polynucleotide encoding the antigen.

5. I have read pending claim 204 and new claim 205 of the subject application and claim 3 of U.S. Pat. No. 6,207,646. I have also read the entire U.S. Pat. No. 6,207,646.

6. I understand that pending claim 204 is directed to a method of treating an allergy in a vertebrate, involving administering to the vertebrate an effective amount of an immunostimulatory nucleic acid in a plasmid. The method entails using an immunostimulatory nucleic acid and an effective amount of an antigen (which is encoded by the plasmid) which stimulates production of allergy associated IgE antibodies in the vertebrate.

7. I understand that new claim 205 is directed to a method for suppressing an allergic response to an antigen in a mammal susceptible to an allergic reaction to the antigen which stimulates production of allergy-associated IgE antibodies in the mammal. The method entails parenterally administering an effective amount of an immunostimulatory nucleic acid in a plasmid and an effective amount of the antigen or the antigen encoded in the plasmid.

8. According to claim 204, administration of antigen is accomplished through administration of a plasmid encoding the antigen. According to claim 205, administration of antigen is accomplished through administration of antigen per se or through administration of a plasmid encoding the antigen.

9. The ability to stimulate an antigen-specific immune response through administration of a polynucleotide which encodes the antigen has been well-known in the art for years, including at the time this application was filed (i.e., January 30, 1996). Some of my earlier papers and patent publications refer to this phenomenon.

10. In the context of allergy immunotherapy, i.e., when offending antigen is administered for the purpose of suppressing the extent of the unwanted immune response (also referred to as desensitization), the desired effect is for the body to respond to the offending antigen in an antigen-specific manner, leading to suppression of the allergic response to that


particular antigen. In this context, administration of an antigen or administration of a polynucleotide encoding the antigen, for example a plasmid, serves the same purpose, i.e., the introduction of the antigen to the body. Once administered, the polynucleotide encoding the antigen is transcribed and translated by the host to yield the antigen. The antigen is then available for the host to generate an antigen-specific immune response.

11. As of the January 30, 1996 filing date of this application, one skilled in the art would have recognized that for administration of an antigen to an individual, administering the antigen could be substituted by administering a polynucleotide encoding the antigen, and this would lead to an antigen-specific immune response and suppression of the allergic response. Thus, as is well-recognized in the art, in terms of the goal of effecting suppression of the allergic response (or desensitization) in allergy immunotherapy, either of the alternatives of antigen per se and antigen as encoded in a polynucleotide can be used.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

May 9, 2002

Date



Dennis A. Carson

CURRICULUM VITAE

Name: DENNIS ANTHONY CARSON, M.D.
14824 Vista del Oceano
Del Mar, California 92014

Date of Birth: May 31, 1946

Place of Birth: New York, New York

Citizenship: United States

Marital Status: Wife - Sandra Coler
Four children

Education: Haverford College - B.A., 1966
Columbia University - M.D., 1970

Postdoctoral Training:

Associate with Dr. Martin Weigert, The Salk Institute, 3/71-6/72
Associate with Dr. Henry Metzger, NIAMDD, 6/72-6/74
Arthritis Foundation Fellow with Dr. J.E. Seegmiller, UCSD, 6/74-12/75

Brief Chronology of Employment:

1970 - 1972 Intern and Resident in Medicine, University Hospital, San Diego, California
1972 - 1974 Clinical Associate, Laboratory of Henry Metzger, M.D., Section on Chemical Immunology, Arthritis and Rheumatism Branch, National Institute of Arthritis, Metabolism and Digestive Diseases, National Institutes of Health, Bethesda, Maryland
1974 - 1975 Postdoctoral Fellow, Laboratory of J. Edwin Seegmiller, M.D., Division of Rheumatology, Department of Medicine, University of California San Diego, La Jolla, California
1976 - 1980 Assistant Member II, Department of Clinical Research, Scripps Clinic and Research Foundation, La Jolla, California
1980 - 1986 Associate Member, Department of Basic and Clinical Research, Scripps Clinic and Research Foundation, La Jolla, California
1986 - 1990 Member, Department of Molecular and Experimental Medicine, Scripps Clinic and Research Foundation, La Jolla, California; Division Head, Clinical Immunology Research Institute, La Jolla, California.
1990 - Adjunct Member, Department of Molecular and Experimental Medicine, The Scripps Research Institute, La Jolla, California.
1990 - Professor, Department of Medicine, University of California San Diego, La Jolla, California
1990 - Director, The Sam and Rose Stein Institute for Research on Aging, University of California San Diego, La Jolla, California

Honors and Awards:

Phi Beta Kappa, 1966; Cope Fellowship, 1966; Alpha Omega Alpha, 1970
Diplomat, American Board of Internal Medicine, 1973
Diplomat, Rheumatology subspecialty, 1975
Arthritis Foundation Fellowship, 1973-1975
Special Fellow of the Leukemia Society of America, 1975-1976
Clinical Investigator Award, NIAMDD, 1976-1977
Lee C. Howley, Sr., Prize for Arthritis Research, 1987
1st Recipient of the Japan Rheumatism Association International Rheumatology Award, 2002

Dennis A. Carson, M.D.

Societies:

American Academy of Arts and Sciences
American Association of Immunologists
American College of Rheumatology
American Society for Clinical Investigation
Association of American Physicians

Other Activities:

Scientific Advisory Board, Edwards Lifesciences LLC
Scientific Advisory Board, Alliance for Lupus Research
Outside Advisory Board, Rheumatic Diseases Core Center, University of Michigan

Research Interests:

Human autoimmune and lymphoproliferative diseases
Human biochemical and molecular genetics

PUBLICATIONS

1973

1. Carson D, Weigert M: Immunochemical analysis of the cross-reacting idiotypes of mouse myeloma proteins with anti-dextran activity and normal anti-dextran antibody. *Proc Natl Acad Sci USA* 70:235-239, 1973.
2. Blomberg B, Carson D, Weigert M: The immune response to dextran in mice, Vol. 11. In: *Third International Convocation of Immunology*. Rose N (ed) p. 285. S. Karger, Basel, 1973.

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3. Weigert M, Raschke WC, Carson D, Cohn M: Immunochemical analysis of the idiotypes of mouse myeloma proteins with specificity for levan or dextran. *J Exp Med* 139:137-147, 1974.
4. Carson D, Metzger H: The separation of rabbit anti-dinitrophenyl IgG antibodies on the basis of combining site depth. *Immunochemistry* 11:355-359, 1974.
5. Carson D, Metzger H: Interaction of IgE with rat basophilic leukemia cells. IV. Antibody-induced redistribution of IgE receptors. *J Immunol* 113:1271-1277, 1974.

1975

6. Carson D, Kulczycki A Jr, Metzger H: Interaction of IgE with rat basophilic leukemia cells. III. Release of intact receptors on cell-free particles. *J Immunol* 114:158-160, 1975.
7. Carson D, Metzger H, Bloch KJ: Serum IgE levels during the potentiated reagin response to egg albumin in rats infected with *Nippostrongylus brasiliensis*. *J Immunol* 114:521-523, 1975.
8. Carson D, Metzger H, Bazin H: A simple radio-immunoassay for the measurement of human and rat IgE levels by ammonium sulfate precipitation. *J Immunol* 115:561-563, 1975.
9. Metzger H, Isersky C, Kulczycki A, Carson D, Buell D: Characterization of receptor for IgE on rat basophilic leukemia cells. In: *Proceedings of the Ninth Leukocyte Culture Conference*. Rosenthal A (ed) Academic Press, New York, 1975.

1976

10. Carson DA, Seegmiller JE: Effect of adenosine deaminase inhibition upon human lymphocyte blastogenesis. *J Clin Invest* 57:274-282, 1976.
11. Carson D, Goldblum R, Keightley R, Seegmiller JE: Immunoreactive adenosine deaminase (ADA) in cultured fibroblasts from patients with combined immunodeficiency disease, Vol. 76A. In: *Advances in Experimental Medicine and Biology*. Müller M, Kaiser E, Seegmiller JE (eds) pp. 463-470. Plenum Publishing, New York, 1977.
12. Carson DA, Goldblum R, Seegmiller JE: Quantitative immunoassay of adenosine deaminase in combined immunodeficiency disease. *J Immunol* 118:270-273, 1977.
13. Carson DA, Seegmiller JE: Relationship of adenosine deaminase and nucleoside phosphorylase deficiency to immunodeficiency. *Arthritis Rheum* 20:S235-S240, 1977.
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15. Carson DA, Kaye J, Seegmiller JE: Lymphospecific toxicity in adenosine deaminase deficiency and purine nucleoside phosphorylase deficiency: Possible role of nucleoside kinase(s). *Proc Natl Acad Sci USA* 74:5677-5681, 1977.

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16. Carson DA, Bayer AS, Eisenberg RA, Lawrance S, Theofilopoulos A: IgG rheumatoid factor in subacute bacterial endocarditis: Relationship to IgM rheumatoid factor and circulating immune complexes. *Clin exp Immunol* 31:100-103, 1978.
17. Carson DA, Lawrance S: Light chain heterogeneity of 19S and 7S anti- γ -globulins in rheumatoid arthritis and subacute bacterial endocarditis. *Arthritis Rheum* 21:438-440, 1978.
18. Willis RC, Carson DA, Seegmiller JE: Adenosine kinase initiates the major route of ribavirin activation in a cultured human cell line. *Proc Natl Acad Sci USA* 75:3042-3044, 1978.
19. Carson DA, Kaye J, Seegmiller JE: Differential sensitivity of human leukemic T cell lines and B cell lines to growth inhibition by deoxyadenosine. *J Immunol* 121:1726-1731, 1978.
20. Robbins DL, Moore TL, Carson DA, Vaughan JH: Relative reactivities of rheumatoid factors in serum and cells. Evidence for a selective deficiency in serum rheumatoid factor. *Arthritis Rheum* 21:820-826, 1978.
21. Slaughter L, Carson DA, Jensen FC, Holbrook TL, Vaughan JH: In vitro effects of Epstein-Barr virus on peripheral blood mononuclear cells from patients with rheumatoid arthritis and normal subjects. *J Exp Med* 148:1429-1434, 1978.

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22. Carson DA, Kaye J, Seegmiller JE: Pathogenic mechanisms in deficiencies of adenosine deaminase and purine nucleoside phosphorylase. In: *Inborn Errors of Immunity and Phagocytosis*. Güttler F, Seakins JWT, Harkness RA (eds) pp. 129-135. MTP Press, England, 1979.
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24. Carson DA, Kaye J, Seegmiller JE: Importance of deoxyribonucleoside trapping by lymphocytes in adenosine deaminase and purine nucleoside phosphorylase deficiency. In: *Inborn Errors of Specific Immunity*. Pollara B (ed) pp. 221-235. Academic Press, New York, 1979.
25. Carson DA, Kaye J: Deoxyribonucleoside toxicity in adenosine deaminase and purine nucleoside phosphorylase deficiency: Implications for the development of new immunosuppressive agents. In: *Enzyme Defects and Immune Dysfunction*. Whelan J (ed) pp. 115-133. Ciba Foundation Symposium 68. Elsevier, Amsterdam, 1979.
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- virus. In: *Immunopathogenesis of Rheumatoid Arthritis*. Panayi GS, Johnson PM (eds) pp. 72-75. Reedbooks Ltd., Chertsey, England, 1979.
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- 1982
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68. Carson DA: New concepts in the immunopathogenesis of rheumatoid arthritis. In: *Recent Progress in Diagnostic Laboratory Immunology*. Nakamura RN (ed) pp. 29-35. Masson Publishing, New York, 1982.
69. Kamatani N, Carson DA: Differential cyst(e)ine requirements in human T and B lymphoblastoid cell lines. *Int Arch Allergy Appl Immunol* 68:84-89, 1982.
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ISSUED PATENTS

<u>Patent</u>	<u>Issued</u>	<u>Title</u>
US4387161	1983	Detection of mycoplasma infection in cell cultures
US4654419	1987	Synthetic polypeptides and antibodies related to Epstein-Barr virus nuclear antigen
US4683295	1987	Method for the preparation of anti-receptor antibodies
US4997926	1991	Deaminase-stable anti-retroviral 2-halo-2',3'-dideoxy
US5028594	1991	Hematopoietic cell destruction by photoactivatable compounds conjugated to amino acids and saccharides
US5068177	1991	Anti-idiotypic antibodies induced by synthetic polypeptides
US5106837	1992	Adenosine derivatives with therapeutic activity
USRE033897	1992	Synthetic polypeptides and antibodies related to Epstein-Barr nuclear antigen

US5116725	1992	Assay for Epstein-Barr virus infection with solid phase bound synthetic polypeptides
US5122448	1992	Assay of anti-Epstein-Barr virus nuclear antigen antibodies with synthetic polypeptides
US5271931	1993	Methods for increasing C1 inhibitor concentrations using interferon-gamma and/or interleukin-6
US5310732	1994	Pharmaceutical compositions containing 2-halo-2'-deoxyadenosines in the treatment of rheumatoid arthritis
US5506213	1996	Administration of 2'-halo-2'-deoxy adenosine to treat inflammatory bowel disease
US5541164	1996	2-halo-2'-deoxyadenosines in the treatment of monocyte-mediated inflammatory disease conditions
US5571510	1996	Method for selective methionine starvation of malignant cells in mammals
US5580859	1996	Delivery of exogenous DNA sequences in a mammal
US5589466	1996	Induction of a protective immune response in a mammal by injecting a DNA sequence
US5679647	1997	Methods and devices for immunizing a host against tumor-associated antigens through administration of naked polynucleotides which encode tumor-associated antigenic peptides
US5703055	1997	Generation of antibodies through lipid mediated DNA delivery
US5747251	1998	Polymerase chain reaction assays to determine the presence and concentration of a target nucleic acid in a sample
US5773570	1998	Vaccine compositions and methods useful in inducing immune protection against arthritogenic peptides involved in the pathogenesis of rheumatoid arthritis
US5804566	1998	Methods and devices for immunizing a host through administration of naked polynucleotides which encode allergenic peptides
US5830877	1998	Dermal and mucosal administration of naked polynucleotides which encode antigens and immunostimulatory peptides
US5840505	1998	L-alanosine for inhibiting adenylyl succinate synthetase activity in methylthioadenosine phosphorylase-deficient tumor cells
US5843943	1998	Preparation of purines and pteridines and analogs for inhibition of ceramide-mediated signal transduction
US5849719	1998	Method for treating allergic lung disease
US5942393	1999	Method for detection of methylthioadenosine phosphorylase deficiency in mammalian cells
US5985847	1999	Devices for administration of naked polynucleotides which encode biologically active peptides
US0010125	2002	Assay for agents that induce chemokinesis
<u>Patent</u>	<u>Issued</u>	<u>Title</u>
WO8502909	1985	Anti-idiotypic antibodies induced by synthetic peptides
WO8601210	1986	Synthetic polypeptides and antibodies related to Epstein-Barr virus nuclear antigen
WO8904662	1989	Adenosine deaminase-stable antiretroviral nucleosides
WO9002570	1990	Methods for increasing C1 inhibitor concentrations by using interferon and/or interleukin-6
WO8908658	1989	Substituted adenine derivatives useful as therapeutic agents
WO9011092	1990	Pharmaceuticals and method for expression of exogenous polynucleotide sequences in a vertebrate for use in immunization and therapy
WO9014835	1990	Rheumatoid arthritis vaccine
WO9409156	1994	PCR assays to determine the presence and concentration of a target
WO9414472	1994	Method for inhibition of cell adhesion to receptors containing selectins
WO9406438	1994	Preparation of adenosine analogs for increasing adenosine release

WO9505853	1995	Method, composition and devices for administration of naked polynucleotides which encode biologically active peptides
WO9517200	1995	Methods for the production and use of anti-idiotypic antibodies using human Ig expressing transgenic animals
WO9517908	1995	Method for selective methionine starvation of malignant cells in mammals
WO9518233	1995	Method for detection of methylthioadenosine phosphorylase deficiency in mammalian cells
WO9528169	1995	Tumor suppressor gene and methods for detection of cancer, monitoring of tumor progression and cancer treatment
WO9531984	1995	Arthritogenic intestinal flora replacement and method and vaccines for the treatment of rheumatoid arthritis
WO9614074	1996	Methods and devices for immunizing a host to tumor-associated antigens through administration of naked polynucleotides which encode tumor-associated antigenic peptides
WO9613277	1996	Methods and devices for immunizing a host through administration of naked polynucleotides which encode antigenic peptides
WO9620710	1996	Compounds for inhibition of ceramide-mediated signal transduction
WO9728259	1997	Gene expression vectors which generate an antigen specific immune response and methods of using the same
WO9732994	1997	Method for inhibiting adenylosuccinate synthetase activity in methylthioadenosine phosphorylase-deficient cells
WO9734002	1997	Antigens for use in inducing immune tolerance to arthritogenic peptides and protection against rheumatoid arthritis
WO9814210	1998	Method for treating allergic lung disease
WO9816247	1998	Immunostimulatory polynucleotide/immunomodulatory molecule conjugates
WO9852948	1998	Preparation of purine, pteridine, thiadiazolopyrimidine, quinazoline, and isoquinoline compounds as inhibitors of ceramide-mediated signal transduction
WO9920791	1999	Method for suppressing multiple drug resistance in cancer cells using adenine synthesis inhibitors
WO9925335	1999	Preparation of benzylidenetetralones and analogs as tubulin binding agents
WO9967634	1999	Early diagnosis of, and determination of prognosis in, cancer based on PCR analysis of human chromosome 9p21 derangements
WO0000491	2000	Preparation of dioxoquinazoloalkanoates and analogs as JNK activation cascade antagonists
WO0020039	2000	Methods and adjuvants for stimulating mucosal immunity
WO0069861	2000	Thiazolopyrimidines useful as TNF- α inhibitors
WO0106990	2001	Use of etodolac in the treatment of cancer

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